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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,190	06/19/2006	Anton Horn	074060.5	7416
27805	7590	04/28/2009		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801				
			EXAMINER	
			TURK, NEIL N	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			04/28/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/564,190	HORN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 14-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 and 14-18 is/are rejected.
- 7) Claim(s) 15-18 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/9/06</u> .  | 6) <input type="checkbox"/> Other: ____ .                         |

## DETAILED ACTION

### ***Claim Objections***

**Claims 15-18** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 recites, “...wherein analyzing the substance...” which does not properly further limit claim 14, such that claim 14 recites “analyzing or preparing...” and thereby the analyzing is not necessary to be chosen. Likewise, claim 16 is dependent upon claim 15 and suffers the same failure to further limit claim 14. Claim 17 recites, “...wherein preparing the substance...” which does not properly further limit claim 14, such that claim 14 “analyzing or preparing...” and thereby the preparing is not necessary to be chosen. Claim 18, in addition to being dependent upon claim 17 so as to suffer the same failure to further limit, also has the problem of reciting “...wherein modifying an analyte” in which the claim 17 provides a list of possible preparations of enriching, depleting, or modifying. As likewise problematic for properly further limiting the claims, the preparation by modifying is not necessary to be chosen.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 14-18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The steps involved in the analyzing or preparing are unclearly recited. What steps are undergone to prepare a biological substance? Additionally, how does one analyze a biological substance only given the recitation to a molded plastic material with at least one surface region being an open-pore three dimensional network? Further, with regard to dependent claims 15-18, what steps are involved so as to identify and quantify the analyte (cl. 15), and then further determine a specific concentration of the analyte (cl. 16)? What steps are involved in the preparation so as to enrich, deplete, or modify an analyte (cl. 17), and further, specifically remove at least one of a phosphate, sugar, or fatty acid moiety from the sample (cl. 18)? Applicant's specification does not provide clear and distinct description for the processes as claimed in claims 14-18 and only generally discusses uses in paragraph [0040] of the pre-grant publication US 2006/0275176.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-10, 14, and 17** are rejected under 35 U.S.C. 102(b) as being anticipated by Shukla et al. (6,416,716), hereafter Shukla.

Shukla discloses a sample preparation device with embedded separation medium (abstract). Shukla discloses a tube 1 with particles of a separation medium 4 (open-pore three dimensional network, where such separation medium defines the surface region) embedded on the inner surface of the tube (molded integrally with the plastic tube). The interior region is said to be the region of the tube where the particles of a separation medium do not exist (lines 40-67, col. 4, fig. 1). Shukla discloses that the tube can be made of polysulfone, among others (line 66, col. 5 – line 9, col. 6).

Shukla discloses that the particles of the separation medium can be porous chromatography materials, active charcoal, and affinity chromatography materials (affinity ligands bound to the surface, also providing to modify an analyte), among others (lines 1-10, col. 7). Shukla discloses that the invention can be used for the preparation of such samples as biological samples, protein containing samples, nucleic acid containing samples, and lipid containing samples, among others (lines 15-24, col. 9).

The Office has interpreted claims 8-10 as a product-by-process claims, since a product-by-process claims is one in which the structural scope of the product is defined at least in part in terms of the method or process by which it is made. In this case, the end product is defined by the following steps: partially dissolving the plastic material on at least a part of the at least one surface region (and chemically activating the surface region, as in claim 9). Applicant is reminded that the product-by-process claim is always to a product. The reference need only to substantially meet the structure of the end product. As set forth above, the disclosure of Shukla meets the structural requirements of the end product of the integral molded part of a plastic material having at least one surface region and an interior region, in which the at least one surface region is an open-pore three-dimensional network as set forth in the instant claims.

Please note that an argument that the applied reference fails to meet all claimed process/limitations of making the end product does not overcome a proper 102/103 rejection because the reference need only to substantially meet all the structure of the end product, see MPEP 2113[R-1] and *In re Fessmann*, 489 F.2d 742, 744 180 USPQ 324, 326 (CCPA 1974).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797